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Food Safety And Inspection Service
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AUDIT REPORT FOR GERMANY
JULY 18 THROUGH AUGUST 6, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Germany's meat inspection system from July 18 through August 6, 2001. The five establishments certified to export meat to the United States were audited. All five establishments were conducting processing operations.

The last audit of the German meat inspection system was conducted in October/November, 2000. Six establishments (Est's A-EV-218, A-EV-36, A-IV-21, A-IV-10, A-EV-139, and A-EV-15) were audited: four were acceptable, and two were evaluated as acceptable/re-review (Est's A-EV-15 and A-EV-218).

The German meat inspection officials removed eight establishments (Ests. A-EV-1277, A-EV-874, A-IV-23, A-EV-15, A-EV-30, A-EV-218, A-IV-21, and A-IV-23) from the list of establishments eligible to export meat and meat products to the United States prior to this new audit.

The major concerns from the October 2000, audit were the following:

- In nine establishments, the HACCP plan did not adequately specify critical limits for each CCP and the frequency with which these procedures will be performed.

- In ten establishments, the HACCP plan did not adequately address the corrective actions to be followed in response to deviations from critical limits.

- In nine establishments, the HACCP plan was not validated to determine that it was functioning as intended.

- In ten establishments, the HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The on-going verification activities of the HACCP program were not adequately performed by either the establishment personnel or by the GOG meat inspection officials.

- In five establishments, the HACCP plan's record-keeping system was not documenting the monitoring of CCPs.

- In three establishments, the HACCP plan was not dated and signed by a responsible establishment official.

- In two establishments, there was no documentation for the pre-shipment document reviews.

- The written SSOP procedures did not address operational sanitation in ten establishments.

- The written SSOP procedures did not address pre- operational sanitation in four establishments.

- The records for SSOP operational sanitation and any corrective actions taken were not being maintained in seven establishments

- GOG meat inspection officials were not monitoring pre-operational sanitation to verify the adequacy and effectiveness of the SSOP in eleven establishments.

- GOG meat inspection officials were not providing adequate daily inspection coverage in the processed products establishments. Inspectors were visiting establishments at variable frequencies such as once a week, twice a week, or once a month. The duration of the visits was between one to two hours in eleven establishments.

- GOG meat inspection officials were not providing inspection coverage for second shift operations in six establishments.

- Periodic supervisory visits were not performed monthly in two establishments. Only one to three internal reviews were conducted per year by local or regional officials. No internal review was conducted in Establishment A-IV-22.

- Product contact equipment (such as containers of edible product, working tables, racks for processed product, edible product conveyor belts, and plastic bins for edible product ready-for-use in the processing room, product receiving room, and boning rooms) was found with fat, grease, dried pieces of meat, and dirt; with open seams that were broken and cracked in four establishments.

- Cross contamination of product such as dripping condensate, from overhead refrigeration units, ceilings, pipes, and air socks that were not cleaned/sanitized daily, was falling onto exposed edible product in the processing rooms; several doors between equipment washing and processing rooms, between edible product receiving and product grinding rooms, between raw product and grinding rooms, and between a processing room and a cooler were opened upwards and puddles of water below the door resulted in dripping dirty water that was observed to fall onto exposed edible product and employees' clothes while passing through these doors; a container of minced meat in the sausage filling room was too close to the hand washing facility creating the potential for cross contamination

from splash water; several containers for edible product ready-for-use and one container with edible product were stored under a catwalk creating the potential for dirt and waste to fall onto product. These deficiencies were observed in four establishments.

- Personnel were not using hygienic work habits to prevent product contamination. Several employees' were observed picking up pieces of meat, used packaging materials, dirty pallets, and a meat hook from the floor; cleaning the floor with a broom; handling dirty containers; and keeping an ax (used for edible product) on an employees' work platform without washing their hands or washing/sanitizing the dirty equipment (then handling edible product) in six establishments.

- Exposed product was not handled in a sanitary manner. Containers of edible product were stacked on each other and exposed product was contacting the dirty bottom of containers; and frozen meat was contacting dirty pallets in Establishment A-EV-139. *Corrected*

- Containers for edible and inedible product and pet food were not identified in four Establishments.

As of end of May 2001, German establishments exported 242,857 pounds of canned products containing processed pork, cured pork, and sausages to the U.S. Port-of-entry rejections were only for transportation damage (0.004 %).

Germany exports only pork processed products to the United States. Restrictions are placed on German fresh pork and beef due to presence of hog cholera and Bovine Spongiform Encephalopathy (BSE).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with German national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the establishment visits. The third involved the on-site visits to the establishments. The fourth was a visit to two laboratories, both performing analytical testing of field samples for the national residue testing program, and culturing field samples for the presence of microbiological contamination with *Salmonella*.

Germany's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and (5) enforcement controls.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and

eliminate product contamination/adulteration are considered unacceptable and, therefore, ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Five establishments were audited (Ests. A-IV-10, A-IV-191, A-IV-22, A-EV-36, and A-EV-139). Four were acceptable and one establishment (A-EV-36) was judged Acceptable Subject to Re-review on the next audit. Details of the audit findings, including compliance with HACCP and SSOPs programs, are discussed later in this report.

At the time of audit no slaughter establishment was U.S. certified. Consequently, carcass testing for generic *E. coli* and *Salmonella* species did not apply. The ready-to-eat products are routinely tested for *Listeria monocytogenes* and *Salmonella.*

As stated above, numerous major concerns were identified during the last audit of the German meat inspection system conducted in October/November 2000.

During this new audit, the auditor determined that some of the major concerns were not adequately addressed and were not corrected.

- The development and implementation of HACCP requirements was not properly implemented and enforced in all the establishments.

- GOG meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of pre-operational sanitation in all of the five establishments.

- GOG meat inspection officials were not providing adequate daily inspection coverage in all five processed products establishments. Inspectors were visiting establishments at variable frequencies such as once a week, twice a week, or once a month. The duration of the visits was between one to two hours.

- GOG meat inspection officials were not providing inspection coverage for second shift operations in two establishments.

- No monthly supervisory visits were conducted in one establishment.

- One employee was not using hygienic work habits to prevent product contamination, such as cleaning the floor with a broom and, without washing hands, handling edible product in the processing room in one establishment. This is a repeat deficiency.

The major concerns during the new audit were the following.

- The development and implementation of HACCP requirements were not properly implemented and enforced in all of the five establishments.

- GOG meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of pre-operational and operational sanitation (SSOP) in all of the establishments.

- The on-going verification activities of the HACCP program were not adequately performed by the GOG inspection officials in all five establishments.

- GOG meat inspection officials were not providing adequate daily inspection coverage in all five establishments. Inspectors were visiting establishments at variable frequencies, such as once a week, twice a week, or once a month. The duration of the visits was between one to two hours.

- GOG meat inspection officials were not adequately providing inspection coverage for second shift operations in two establishments.

- Monthly supervisory reviews were not conducted in one establishment.

- Inedible product destined for rendering was not denatured/decharacterized or under proper security before shipping in one establishment.

- Intralaboratory and/or interlaboratory check samples for the quality assurance programs were inadequate. In addition, when the percent recovery results for check samples were unacceptable or had fallen below the established acceptable limit, the corrective actions that were taken, if any, not documented.

- The control of *Listeria monocytogenes* is not included in the HACCP plan in establishments producing ready-to-eat products.

- Establishment officials have a surveillance program for *Listeria monocytogenes* testing between one to five samples per month in establishments producing ready-to-eat products. A few samples were also taken for environmental contamination in each establishment.

- The sanitizer was not maintained at the required temperature during the operation in the product receiving room in Establishment A-EV-36.

- Inedible product was not denatured/decharacterized or under secure conditions before shipping for rendering in Establishment A-EV-36.

Entrance Meeting

On July 18, 2001, an entrance meeting was held at the Berlin offices of the Federal Institute for Health Protection of Consumer and Veterinary Medicine (BgVV), and was attended by Dr. Ekkehard Weise, Director and Professor, Food Safety and Hygiene (FSH), BgVV; Dr. Peter Paul Hoppe, Deputy Director, Food Safety and Hygiene; Ms. Sabine Lieberz, Agricultural Specialist, Foreign Agricultural Service (FAS); Ms. Kerstin Kruger, Agricultural

Assistant, Foreign Agricultural Service (FAS), American Embassy in Berlin; Mr. Richard F. Brown, Senior Equivalence Officer, International Policy Staff, FSIS; Dr. Judd Giezentanner, International Audit Staff Officer, FSIS and Dr. Faiz R. Choudry, International Audit Staff Officer, FSIS.

Topics of discussion included the following:

1. Welcome by Dr. Ekkehard Weise, Director, FSH, BgVV and explanation of the German meat inspection system.

2. Overview of the National Residue Program.

3. Discussion of the previous audit report.

4. The auditor provided copies of the data-collection instruments and a copy of the current Quarterly Regulatory and Enforcement Report. Upon inquiry, it was determined that Germany does not make similar information available to the public.

5. The audit itinerary and travel arrangements. Subsequent to that meeting, the USDA team divided into two subgroups and pursued their individual audit goals.

6. Discussions regarding what BgVV can and cannot do in relation to the States, especially in the area of the listing and delistment of establishments.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Germany's inspection system in October/November 2000.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted reviews of inspection system documents pertaining to each establishment audited. These records reviews were conducted at each establishment. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels, and animal raising claims.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Compliance with SSOPs, HACCP programs.

- Sanitation and processing inspection procedures and standards.
- Control of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records, including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents:

- The development and implementation of HACCP requirements was not properly implemented and enforced in all the establishments.

- GOG meat inspection officials were not adequately monitoring/verifying the adequacy and effectiveness of pre-operational and operational sanitation (SSOP) in all establishments.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Germany as eligible to export meat products to the United States were government employees, receiving no remuneration from either industry or establishment personnel.

The German oversight system is potentially unique to countries that export to the United States. The responsibilities of the various levels of authority within Germany have been previously outlined in FSIS' report of the November 2000 audit of Germany and in the European Commission (EC) report from Directorate F, DG (SANCO)/1218/2000. The most relevant responsibilities of the central government are to participate and negotiate during new or revised EC legislation, to interpret and clarify EC Directives and federal laws and regulations, and to pass these documents on to the state governments. These are then passed on to the lower levels of authority by the state. However, although compliance is mandated, the states and the various lower levels of authority can create corresponding regulations, directives, and ordinances of their own, as long as they meet the minimum requirements mandated by the "higher" authority. These state-and local-level documents are normally used for clarification and administrative purposes only.

To understand the levels of authority that receive these regulatory documents, the organizational structure within Federal Republic of Germany needs to be understood. Germany consists of the sixteen Federal States of Germany. Each *Land* or state in Germany is further divided into smaller territories. Using terminology adopted by the EC, each state is divided into regions (or Regierungsbezirk) and each region is divided into local districts (or Ländkreis.). In addition, each local district can have one or more city governments (or Kreisfreie Städte) within their borders. At the present time, there are only two states with establishments that are certified to export to the United States, Bavaria and Lower Saxony. The various levels of authority work together to implement Germany's meat inspection program.

The supervision and authority established or delegated by the state and by the local authorities varies. The inspectors and veterinarians that work within these levels of authority are not necessarily accountable to the "higher" levels. The meat inspectors, food inspectors and veterinarians that actually perform the daily inspection activities are not normally hired or paid by either the state or the region. Disciplining or firing resident inspectors and veterinarians can not be dictated by the state or regional governments. These "higher" levels of authority can only recommend action against a poor performing government employee working in an EC or U.S. approved establishment. In addition, the potential exists that the supervisor who performs monthly supervisory visits in these establishments is not an employee of either the state or the regional offices. However, in Lower Saxony, the state has the authority to replace a district-paid veterinarian with a state-paid veterinarian if the local district refuses to correct a performance problem.

Although direct and accountable supervision is different than it exists in the U.S., veterinarians within Germany all receive approximately the same training and operate at a high level of professionalism and trust. The additional experience, education, and examination of hired government veterinarians is used as a means of identifying performance weaknesses. The performance of responsibilities and duties of these veterinarians is, however, rarely questioned. Actual visits to determine competence by the "higher" levels of authority may not be routinely performed or documented and are not part of any written supervisory plan. Although there are detailed instructions of what to do when visiting a "lower" level authority, including visits to an establishment, the central and state governments rely heavily upon the results of EC and U.S. audits of their inspection system and appear to have a reactive system of maintaining compliance rather than a preventative system of maintaining compliance.

In addition, part of the responsibility of the regions is to approve establishments for EC and U.S. markets and to withdraw federal approval from these establishments. The regional office notifies the state office of each approval and withdrawal. The state office then notifies the Federal Institute in Berlin. The federal and state offices do not visit these establishments as a result of the approval and do not supervise or question the validity of a region's decision to approve or withdraw an establishment. However, the regions work closely with the local veterinarians to secure compliance for the approvals and have extensive documentation of their pre-approval inspections of the establishments.

Establishment Audits

Five establishments were certified to export meat products to the United States at the time this audit was conducted. All five establishments (Est's A-IV-10, A-IV-22, A-IV-191, A-EV-36, and A-EV139) were visited for on-site audits. In all five of the establishments visited, both German inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. Four establishments (Est's A-IV-10, A-IV-22, A-IV-191, and A-EV-139) were found acceptable. Establishments A-EV-36 was rated acceptable subject to re-review on the next audit because of some deficiencies regarding sanitation and the condition of facilities, which are mentioned later in this report.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The Staatliches Veterinarunter-suchungsamt, Federal Land der Lower Saxony, Laboratory for Residues of Veterinary Drugs and Microbiology in Hanover was audited on July 19, 2001. Another Veterinary Drug Residues Laboratory, Andesuntersuchungsanstalt fur das Gesundheits-u Veterinarwesen Sachsen Standort, in Dresden (Saxony) was audited on July 20, 2001. Except as noted below, both laboratories had effective controls in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done.

The following concerns arose as a result of these laboratory audits:

- Intralaboratory and/or interlaboratory check samples for their quality assurance program was inadequate for chlorinated hydrocarbons, polychlorinated biphenyls, sulfonamides, organophosphates, trace elements, hormones, chloramphenicol, ivermectin, antibiotics, *Salmonella,* and *Listeria monocytogenes*.

- When percent recovery results for check samples of oxytetracycline were unacceptable (fallen below the established acceptable limit 80%), no corrective actions were taken and documented.

Establishment Operations by Establishment Number

The following operations were being conducted in the five establishments:

Pork and beef cooked /smoked sausages in jars, and canned and smoked sausages - three establishments (Ests. A-IV-10, A-EV-36, A-IV-139)
Smoked and air dried, cured hams – two establishments (Ests. A-IV-191 A-IV-22)

SANITATION CONTROLS

Based on the on-site audits of establishments, Germany's inspection system had controls in place for water potability records; back-siphonage prevention; hand washing facilities; separation of operations; sanitizers; temperature controls; lighting; operations work space; ventilation; dry storage areas; welfare facilities; outside premises; and personal dress and habits.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

Basic Establishment Facilities

- The sanitizer was not maintained at the required temperature during the hog carcass trimming operation in the receiving room in Establishment A-EV-36. Establishment officials took corrective action immediately and preventive measures were proposed to GOG inspection officials to prevent recurrence.

Condition of Facilities and Equipment

- A few racks for exposed frozen edible product ready-for-use in the product receiving room were found with old fat residue, black discoloration, and dirt in Establishment A-EV-36. Establishment officials took corrective action immediately and proposed corrective/preventive measures to meat inspection officials.

Personnel Hygiene and Practices

- One employee was observed cleaning the floor with a broom and, without washing her hands, handling edible product in the processing room in Establishment A-EV-36. Establishment officials took corrective action immediately.

ANIMAL DISEASE CONTROLS

Germany's inspection system had no slaughter establishments that were U.S. certified. Therefore, with the exception listed below, the risk factors were not evaluated.

- Inedible product was not denatured/decharacterized or under secure conditions before shipping for rendering in Establishment A-EV-36.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. About eighty-nine positive cases for Bovine Spongiform Encephalopathy (BSE) were reported in Germany. APHIS has restrictions on importation of meat and other animal products from Germany due to hog cholera and BSE.

RESIDUE CONTROLS

Germany's National Residue Testing Plan for 2001 was being followed and was on schedule. German inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and the storage and use of chemicals (see Attachment E).

SLAUGHTER/PROCESSING CONTROLS

Except as noted below, the German inspection system had controls in place to ensure adequate boneless meat reinspection; restricted product control; ingredients identification; control of restricted ingredients; formulations; packaging materials; label approvals; processing equipment, processing records; empty can inspection; filling procedures; container closure examination; and post-processing handling.

Currently there are no slaughter establishments certified for export to the United States.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis / Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

With the exceptions listed below, the HACCP programs were found to meet the basic FSIS regulatory requirements:

- The HACCP plan did not adequately conduct a hazard analysis that included food safety hazards likely to occur in Establishments A-EV-36, A-IV-191, and A-IV-22.

- The HACCP plan did not adequately specify critical limits, monitoring procedures, and the monitoring frequency performed for each CCP in Establishments A-IV-10, A-EV-36, and A-EV-139.

- The HACCP plan did not adequately address the corrective action to be followed in response to a deviation from a critical limit in Establishment A-IV-22.

- The HACCP plan was not validated to determine that it was functioning as intended in Establishments A-EV-36, A-EV-139, and A-IV-10.

- The HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The on-going verification activities of the HACCP program were not adequately performed by the establishment personnel. These deficiencies occurred in Establishments A-IV-10, A-EV-36, A-EV-139, and A-IV-191.

- The HACCP plan's record-keeping system was not documenting the monitoring of CCPs in Establishment A-IV-10.

Testing for Generic *E. coli*

E. coli testing is not required in Germany's establishments that are certified to export meat products to the U.S. because APHIS regulations prohibit the import of meat from hogs and

cattle slaughtered in Germany. Germany obtains meat for U.S. export from hogs and cattle slaughtered in a country eligible to export slaughtered hogs and cattle to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The German inspection system controls regarding boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, and the importation of only eligible meat products from other counties for further processing (i.e. only from eligible countries and certified establishments within those countries) were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Salmonella testing is not required in Germany's establishments that are certified to export meat products to the United States because APHIS regulations prohibit the import of meat from hogs and cattle slaughtered in Germany. Germany obtains meat for U.S. export products from hogs and cattle slaughtered in the third country that is eligible to export meat to the United States.

Species Verification Testing

At the time of this audit, Germany was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in all establishments audited in accordance with FSIS requirements.

Listeria monocytogenes

The following deficiencies were noted with Germany's testing program:

- The control of *Listeria monocytogenes* is not included in the HACCP plan in establishments producing ready-to-eat products.

- Establishment officials have a surveillance program for *Listeria monocytogenes* testing between one to five samples per month in establishments producing ready-to-eat products. A few samples were also taken for environmental contamination in each establishment.

Monthly Reviews

These reviews were being performed by the City or District Veterinarians. These positions are similar to FSIS' Inspector-in-Charge and Circuit Supervisor, respectively.

The internal review program was applied equally to both export and non-export establishments. In four establishments, reviews were conducted monthly and in one establishment no monthly review was performed. The records of audited establishments were kept in the Regional or District Inspection offices, and were routinely maintained on file for a minimum of 2 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, the Regional office is empowered by the State to conduct an in-depth review, and a recommendation for certification is reported to BgVV in Berlin through the State Inspection system.

Enforcement Activities

The domestic and exporting country requirements are enforced by the regional offices. This authority is delegated to them by the State. The Regions are thereby empowered by law to take corrective measures, penalize establishments and suspend or withdraw their licenses to operate. Other federal, state, and local law enforcement agencies are involved in investigations and control.

The meat inspection system is administered independently by each of the 16 states. Each state controls, implements, and enforces mandatory Fleischhgiene-Verordnung (FIH)- federal meat hygiene regulations. The district or city inspectors and veterinarians visit these establishments at variable frequencies: once a week, once a month and between one to two hours each visit. Adequate daily inspection coverage to processed products establishments is not provided. Second shift operations mostly are not covered in Establishments A-IV-10 and A-IV-191. The inspection and establishment system documents are maintained in the City, District, or Regional office. Information is not sent to the BgVV national headquarters in Berlin.

The inspectors, in addition to periodic meat inspection activities, are also responsible for the inspection and compliance (enforcement) of the inspection laws for all kinds of food products including vegetables, cereals, bakeries, honey, fish, egg, milk, and poultry products. They are also responsible for body-contact items, such as eyeglasses, cosmetics, drinking glasses, jewelry, and clothes.

Controls were in place to ensure adequate export product identification, inspector verification, export certifications, a single standard of control throughout the establishment, and adequate controls for security items, shipment security, and product entering the establishments from outside sources.

Exit Meetings

An exit meeting was conducted in Berlin on August 6, 2001. The German participants were Dr. Ekkehard Weise, Director and Professor, Food Safety and Hygiene (FSH), BgVV; Dr. Peter Paul Hoppe, Deputy Director, Food Safety and Hygiene; Ms. Joani Dong, Agricultural Attache, Foreign Agricultural Service (FAS), American Embassy in Berlin; Ms. Kerstin Kruger, Agricultural Assistant, (FAS), American Embassy in Berlin; Ms. Sabine Lieberz, Agricultural Specialist, (FAS), U.S. Embassy in Berlin; Mr. Richard F. Brown, Senior Equivalence Officer, International Policy Staff, FSIS; Dr. Judd Giezentanner, International audit Staff Officer, FSIS, and Dr. Faiz R. Choudry, International audit Staff Officer, FSIS.

A second meeting was conducted with the European Commission (EC) in Brussels, Belgium on August 7, 2001. The EC participants were Dr. Paolo Dhostby, DG, Health and Consumer Protection Directorate General (SANCO), Unit E-3, Dr. Jennifer Egan, FVO, Veterinary Inspector Food of Animal Origin in Dublin. The participant from Germany was Dr. Peter-Paul Hoppe. The participants from FSIS were Mr. Richard F. Brown, Dr. Judd Giezentanner, and Dr. Faiz R. Choudry.
The following topics were discussed:

1. The SSOPs were found to meet the basic FSIS regulatory requirements in all five establishments audited, with the following variations:

    - GOG meat inspection officials were not adequately monitoring pre-operational and operational sanitation to verify the adequacy and effectiveness of the sanitation SSOP in all five establishments.

2. Sanitation Controls

    Cross-Contamination: In the area of cross-contamination, actual product contamination and the potential for product contamination was found in one out of five of the establishments audited. GOG inspection officials took corrective actions. Specific findings for each establishment audited on-site can be found in Attachment F to this report. Examples of findings of actual product contamination include:

    - A few racks for exposed frozen edible product in the product receiving room that were ready for use, were found with old fat residue, dirt, and black discoloration.

    - The sanitizer was not maintained at the required temperature during the operation in the product receiving room.

    Personnel were not observing good hygienic work habits to prevent product contamination:

    - An employee was not using hygienic work habits to prevent product contamination such as cleaning floor with broom and, without washing her hands, handling edible product in one establishment. This is a repeat deficiency.

The HACCP programs were reviewed during the on-site audits of all five establishments. The auditor found the following deviations from FSIS regulatory requirements :

- The HACCP plan did not adequately conduct a hazard analysis that included food safety hazards likely to occur in three establishments.

- The HACCP plan did not adequately specify critical limits, monitoring procedures, and the monitoring frequencies performed for each CCP in three establishments.

- The HACCP plan did not adequately address the corrective action to be followed in response to a deviation from a critical limit in one establishment.

- The HACCP plan was not validated to determine that it was functioning as intended in three establishments.

- The HACCP plan did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequencies with which these procedures will be performed. The on-going verification activities of the HACCP program were not adequately performed by the establishment in four establishments.

- The HACCP plan's record-keeping system was not documenting the monitoring of CCPs in one establishment.

3. Inspection System Controls

- The ongoing verification activities of the HACCP program were not adequately performed by the GOG inspection officials in all five establishments.

- GOG meat inspection officials were not providing adequate daily inspection coverage in all five establishments. Inspectors were visiting establishments at variable frequencies, such as once a week, twice a week, or once a month. The duration of the visits was between one to two hours.

- GOG meat inspection officials were not adequately providing inspection coverage for second shift operations in two establishments.

- Monthly supervisory reviews were not conducted in one establishment.

- Inedible product destined for rendering was not denatured/decharacterized or under proper security before shipping in one establishment.

4. Laboratory Audits

- Intralaboratory and/or interlaboratory check samples for the quality assurance programs were inadequate. In addition, when the percent recovery results for

check samples were unacceptable or had fallen below the established acceptable limit, the corrective actions that were taken, if any, not documented.

Dr. Ekkehard Weise, Director and Professor, Food Safety and Hygiene, BgVV and Dr. Peter Paul Hoppe, Deputy Director, Food Safety and Hygiene, indicated that they would take the necessary steps to ensure that corrective actions and preventive measures, including HACCP and SSOP programs as promised during the audits and exit meetings in individual establishments, would be implemented.

CONCLUSION

The German meat inspection system had several repeat deficiencies and new deficiencies. One repeat deficiency of major concern was the lack of adequate daily inspection coverage. This current team audit was conducted as a result of the deficiencies found during the early FY 2001 audit. To secure a clear picture of the inspection system's response to observed non-compliances, all of the deficiencies noted above should be reviewed jointly with the facts presented under the Government Oversight section of this report. Potential weaknesses in the oversight system of the Federal Republic of Germany, as implemented by the Federal States of Germany, and enforced by the regions within each state may be evidenced by the findings presented in this report and summarized below.

Five establishments were audited: four were acceptable and one was evaluated as acceptable/re-review. During the on-site audits with establishment representatives and government officials from the regional and district offices, assurances were made to FSIS personnel that they would ensure prompt compliance. However, these assurances were also made during and/or at the conclusion of the FY 1999, FY 2000, and October/November 2000 audits with only minor corrective actions taking place between audits. In addition, the BgVV authorities in Berlin were not able to guarantee the immediate implementation of adequate daily inspection coverage of U.S. export establishments, as required by FSIS at the exit conference on August 6, 2001. State officials were faxed a letter during the exit conference in Berlin, requesting confirmation ("today, if possible") that adequate daily inspection coverage would be implemented on August 7, 2001.

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ATTACHMENTS

A. Data collection instrument for SSOP
B Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory audit forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
A-IV-10	√	√	√	√	√	√	√	√
A-IV-191	√	√	√	√	√	√	√	√
A-IV-22	√	√	√	√	√	√	√	√
A-EV-36	√	√	√	√	√	√	√	√
A-EV139	√	√	√	√	√	√	√	√

Acceptable √ Deficiency *

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. 12, which was a cold-storage facility) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing and documenting pre-shipment document reviews as required.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Haz. analysis –all ID'ed	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. Procedures	10. Adequate documentation	11. Dated and signed	12. Pre-shipment doc. reviews
A-IV-10	√	√	√	√	√	*	√	*	*	*	√	√
A-EV-191	√	*	√	√	√	√	√	√	*	√	√	√
A-IV-22	√	*	√	√	√	√	*	√	√	√	√	√
A-EV-36	√	*	√	√	√	*	√	*	*	√	√	√
A-EV-139	√	√	√	√	√	*	√	*	*	√	√	√

Acceptable √ Deficiency *